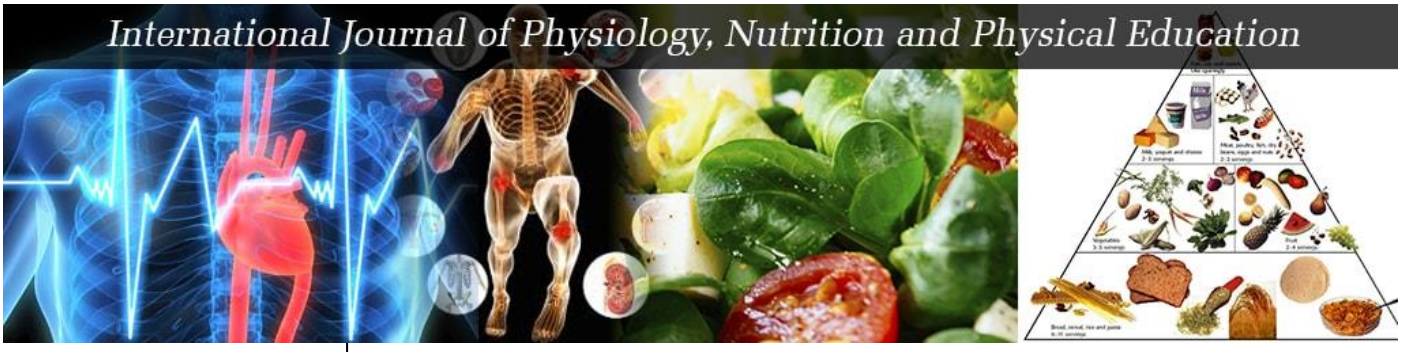

ISSN: 2456-0057
IJPNPE 2023; 8(1): 25-37

www.journalofsports.com
Received: 24-11-2022
Accepted: 27-12-2022

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Comparison of ELTGOL Therapy versus ACBT on Breathlessness, cough and sputum production; Exercise capacity and quality of life in middle aged bronchiectasis patients

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DOI: https://doi.org/10.22271/journalofsport.2023.v8.i1a.2663

Abstract
Respiratory physiotherapeutic techniques have gained wide acceptance in reducing the pulmonary symptoms and improving the quality of life of Bronchiectasis patients. This study aims to compare the efficacy of ELTGOL technique (L' Expiration Lente Totale Glotte Ouverte en decubitus Lateral) which is a lesser known but increasingly popular airway clearance technique, versus ACBT (Active cycle of breathing techniques) which is the standard airway clearance technique, in improving the pulmonary impairments, exercise capacity and quality of life in middle aged bronchiectasis patients. 40 bronchiectasis patients were assessed and were divided into two groups- Group A and Group B. Each group had a total of 20 patients. Patients in Group A underwent ELTGOL therapy and Group B received ACBT as the airway clearance technique. The Breathlessness cough and sputum scale score, 6- minute walk distance and St. George Respiratory questionnaire score were assessed before and after 4 weeks of the said interventions. All the data analysis was done using SPSS software version 26. The study concluded that individually, ELTGOL and ACBT had a statistically significant role in improving the pulmonary impairments, exercise capacity and quality of life in middle aged bronchiectasis patient. However, there was insignificant difference between ELTGOL and ACBT in terms of improving the pulmonary impairments, functional capacity and health related quality of life in middle aged Bronchiectasis patients.

Keywords: ACBT, ELTGOL, physiotherapy, bronchiectasis, BCSS score, SGRQ score, breathlessness, quality of life, exercise capacity

1. Introduction
Bronchiectasis is a progressive obstructive airway disorder and is defined by permanent and abnormal airway dilatation. It is characterized by chronic cough and sputum production. It usually follows an infection following airway inflammation. A HRCT of Bronchiectasis patient would show an increase in the inner diameter of the bronchus more than the adjacent pulmonary artery and visualization of bronchus in the outer lung fields suggesting airway dilatation [1]. There are several etiological factors associated with Bronchiectasis *viz.* post-infection, muco-ciliary disorders, extremes of age, aspiration, malnutrition, socioeconomic disadvantage, immune disorders like HIV infection or allergic bronchopulmonary aspergillosis, etc. [2]. According to several studies, it was found that Haemophilus influenzae, Pseudomonas aeruginosa and Streptococcus pneumoniae are most commonly involved pathogens in Bronchiectasis [3, 4]. These pathogens lead to inflammation in the airways. Neutrophils, lymphocytes and Macrophages are mostly involved in the inflammatory process in bronchiectasis [5, 6] which causes release of inflammatory mediators particularly protease and elastase that causes bronchial dilation and mucous hypersecretion [7]. This increased bronchial wall diameter aids bacterial colonization leading to recurrent infection and mucus production and so the vicious cycle continues.
Muco-ciliary clearance is hampered due to this structural changes and mucous clogging which makes Bronchiectasis a kind of Obstructive airway disease [8]. This obstructive nature of Bronchiectasis due to the structural changes and mucous clogging affects the gas exchange leading to Breathlessness which is one of the causes 7 of mortality due to Bronchiectasis [9].

A pulmonary function test study found that this obstructive pattern seen in bronchiectasis is mostly due to the small and medium airway involvement [10]. Anatomical studies by Whitwell have explained the obstructive nature of bronchiectasis [11]. Apart from the pulmonary impairments, it has been seen that Bronchiectasis also impacts the functional capacity and quality of life. A cross sectional study on 139 middle aged bronchiectasis patients by José *et al*. have shown that the impairment in the functional capacity of these subjects is directly proportional to the severity of the pulmonary impairments [12]. A Study by Ozalp *et al*., has shown that exercise capacity, perception of fatigue and quality of life is also affected in Bronchiectasis [13].

Bronchiectasis is now a growing global health problem. It has been observed that bronchiectasis is more prevalent in the developing nations. In a recent observational cohort study by the Respiratory Research Network of India in September 2019, out of the total population of Bronchiectasis studied, about 30.7% of patients had moderate Bronchiectasis and about 36.1% had severe Bronchiectasis as per Bronchiectasis Severity Index [9].

However, respiratory physiotherapeutic manoeuvres have gained wide acceptance in reducing the pulmonary symptoms and alongside improving the quality of life of the affected individuals. This obstructive nature of Bronchiectasis can be brought under control using several airway clearance techniques [14]. In bronchiectasis, the goal of physiotherapeutic treatment is to prevent the progression of the disease and improve the quality of life [14].

Recently a lesser known but increasing popular technique called ELTGOL (L' Expiration Lente Totale Glotte Ouverte en decubitus Lateral) [15] has been introduced which is simple, easy to administer, well tolerated and inexpensive airway clearance technique and also supported by several randomized controlled trials [16, 17] in Bronchiectasis subjects. Airway clearance by ELTGOL therapy is proven by two phase-gas liquid flow theory [18]. According to this theory, an effective mucous clearance can be achieved if the expiratory flow velocity exceeds the inspiratory flow velocity producing a net shear force which may mobilize the mucous in the direction of the expiratory flow. In this technique, the volume of the dependent lung is reduced by placing the patient in the lateral decubitus position and so limiting breathing to expiratory reserve volume [19] which in turn reduces total cross-sectional area of the peripheral airways where mucus is primarily clogged. As the airway diameter decreases, the velocity of airflow in the peripheral airways is increased [20] hence mobilizing the secretions.

Active cycle of breathing techniques (ACBT) is commonly used airway clearance technique for Bronchiectasis [21, 22] for its ease to administer and patient acceptance [23]. It is repetitive cycle which comprise of 3 components-Breathing control, Thoracic expansion exercises and forced expiratory techniques [24]. Breathing control is a period of relaxed breathing at subject's own rate. It comprises of relaxed tidal breathing which reduces the work of breathing, assists in recovery from shortness of breath and prevents bronchospasm [25]. Thoracic expansion exercises comprise of slow and deep inspiration with an inspiratory pause of about three seconds which allows collateral ventilation followed by a slow sustained exhalation. This technique is based on phenomenon of interdependence [25]. Forced expiration techniques involves 1 or 2 forceful huffs followed by a cough. It works on the principle of equal pressure point [25]. With huffing, the secretions are mobilized to the proximal airways which is then expelled through coughing.

Breathlessness, Cough and Sputum scale (BCSS) was developed to effectively measure the severity of respiratory symptoms. The BCSS records symptoms in a 5-point Likert like scale in which zero represents improvement symptoms and scores towards 4 indicating worsening of symptoms [26]. It is commonly used in patients with COPD but Nicolini *et al*. in their study involving bronchiectasis [27] successfully used BCSS as an outcome measure to assess respiratory symptoms. BCSS provides a simple and robust quantification of symptoms that is sensitive to the effects of treatment and could therefore be used to assess therapeutic interventions. It has good reliability and validity for use in patients with respiratory disorders [28].

The extrapulmonary effects of bronchiectasis includes reduced exercise capacity [13]. Increased sputum production and progressive airflow obstruction in bronchiectasis causes expiratory flow limitation, which further causes dynamic hyperinflation and increased work of breathing which is physiologically responsible for reduction in maximal mechanical power output i.e the exercise capacity [29]. Thus, any improvement in the respiratory symptoms may have an impact in the exercise capacity which is usually evaluated by 6-minute walk test (6MWT) which is a useful measure of functional capacity and is validated and reliable in patients with bronchiectasis [30, 31].

Any health-related quality of life (HRQL) questionnaires allows the therapist to understand the impact of disease on a patient's daily life. St George's respiratory questionnaire (SGRQ) is one such health-related quality of life questionnaire which is validated and is reliable for use in bronchiectasis patients [32] to understand the impact of disease and treatment strategies on their quality of life. It comprises of 3 domains- symptoms, activity, and impact. The symptoms domain includes questions related to symptomatology including the duration and frequency of breathlessness, wheeze, cough, sputum production. The activity domain includes questions related to the activities limited due to breathlessness. The impact domain includes questions related to activities of daily living altered by the disease.

As there is a lack of evidence of the superiority of any airway clearance technique used in bronchiectasis, there was a need to investigate and compare the effects of the newer developed techniques with standardized treatment. Airway clearance techniques not only improves the sputum production but also improves the quality of life [33]. ELTGOL has gained wide popularity in the West as an airway clearance technique whereas ACBT is a standardized treatment followed in India. Hence, this study aims to compare the efficacy of ELTGOL versus ACBT in improving the pulmonary impairments, exercise capacity and quality of life in middle aged bronchiectasis patients.

1.1 Hypothesis

Null hypothesis: There is no difference between the effectiveness of ELTGOL and ACBT in affecting the Breathlessness, cough and sputum scale (BCSS) score, exercise capacity and quality of life (SGRQ score) in middle aged bronchiectasis patients after supervised sessions of 4 weeks.

Alternate hypothesis: There is a difference between the effectiveness of ELTGOL and ACBT in affecting the Breathlessness, cough and sputum scale (BCSS) score, exercise capacity and quality of life (SGRQ score) in middle

aged bronchiectasis patients after supervised sessions of 4 weeks.

1.2 Objectives of the study

1. To assess the BCSS score, 6-minute walk distance and SGRQ score in patients undergoing ELTGOL technique (GROUP A), pre and post 4 weeks intervention.
2. To assess the BCSS score, 6-minute walk distance and SGRQ score in patients undergoing ACBT (GROUP B), pre and post 4 weeks intervention.
3. To compare the effect of ELTGOL versus ACBT on BCSS score, 6-minute walk distance and SGRQ score.

2. Materials and methods

2.1 Materials

Subject information sheet, Consent form, Case record form, Plinth, Stethoscope, Pulse oximeter, Stopwatch, Sputum mug, Mouth-piece, Breathlessness, Cough and Sputum scale, St. George Respiratory questionnaire, 30 m corridor, SGRQ application

2.2 Methodology

1. **Study Design**: Experimental, Comparative study.
2. Location of The Study-Physiotherapy OPD of Tertiary health care Centre.
3. Study Population- Bronchiectasis patients.
4. Duration of Study-18 months
5. **Sampling Technique:** Convenient sampling with random allocation.
6. **Sample Size**: Based on the feasibility and availability of target population in the study frame, the sample size was calculated to be 68. However, due to Covid-19 pandemic, the sample size was amended with prior permission of Institutional Ethics Committee to 40.
7. **Inclusion Criteria**: Patients who are Clinically stable, Those with Moderate to severe bronchiectasis as per Bronchiectasis Severity Index [34], Those within the Age of 36-55 [35], Both males and females [35], Those with Daily sputum volume more than 20ml for 3 consecutive days.
8. **Exclusion criteria:** Those with History of smoking, clinically diagnosed Asthmatic patients [36], Physician diagnosed COPD [37], Clinically or radiologically confirmed Interstitial lung disease, Clinically or radiologically confirmed Pneumonia, Active tuberculosis, Haemoptysis, Osteoporosis, Flail Chest, Tracheostomy patients, Recent history of myocardial infarction
9. **Methodology**: After the approval from the Institutional Ethics Committee (IEC), subjects were selected depending upon the inclusion and exclusion criteria. Subjects were explained about the study in the language they comprehended well and Consent from the participants was taken through a consent form in their own preferable language. Participants were randomly allocated into two *viz*. Group A (ELTGOL) and Group B (ACBT). Demographic data including Name, Age, place of residence, medical and surgical history, clinical examination including respiratory assessment through auscultation and vitals assessment including respiratory rate, heart rate and blood pressure was taken at the beginning of the study. Radiological investigations available with the subjects were assessed and documented. Outcome measures *viz*. Breathlessness cough and sputum scale, and St George Respiratory questionnaire was taken and functional evaluation by 6-minute walk test was conducted at the beginning of the study. The BCSS score was noted. SGRQ total score was measured using the SGRQ application. 6- minute walk distance was measured by the test and subject's oxygen saturation was monitored throughout the test. Each group underwent a common treatment protocol of Nebulization with mucolytics or saline prior to the intervention. ELTGOL and ACBT to the respective groups were performed thrice a week for 4 weeks. After 4 weeks, BCSS Score and SGRQ Score was again assessed and noted. 6-minute walk test was conducted and the 6-minute walk distance was measured. Subject's oxygen saturation was monitored throughout the test. The outcome within the group and between the two groups were compared using statistical tools.
10. **Intervention for Group A– ELTGOL:** Auscultation over the lung zones was done to identify the affected side and zone. Subject were given a pillow under the head and were instructed to assume a decubitus position placing the most affected side inferiorly [19]. A mouthpiece was given to ensure open glottis and to maintain airway patency i.e., to decrease airway compression. Subject were first asked to breathe normally. They were then instructed to perform slow and prolonged expirations with the glottis open, from the functional residual capacity (FRC) to the residual volume (RV). In addition, during the exhalation, chest and abdominal compressions were performed by the therapist to enhance the technique's efficacy. 10 repetitions of such breathing pattern were performed with a 1–2-minute interval between them totalizing approximately 8 minutes in one position. Subject was moved to the less affected / contralateral side as well and the same breathing pattern was repeated and the mouthpiece was retained. Total treatment time continued up to 20 minutes or as per subject's limit or when sputum was expectorated.
11. **Intervention for Group B- ACBT:** Subjects were made to sit comfortably on the plinth in the semi-fowler's position with adequate support to the head and below the knees [38]. Breathing control: Subject were allowed to breath at the normal rate and depth using the lower chest. Thoracic expansion exercises: Subject were made to perform active shoulder flexion with deep inspiration and hold the breath for about 2-3 seconds and while returning to neutral, were made to perform pursed lip exhalation. Similarly, subject performed active shoulder abduction with deep inspiration and while returning to neutral, performed pursed lip exhalation. This continued for about 10 repetitions. Forced expiratory technique: Subject were asked to take a deep breath and while keeping the mouth open in O shape, perform forceful contraction using their abdominal muscles (huff). Patient were allowed to cough only after the end of the cycle with FET. After the patient was stable followed one cycle of ACBT, the next cycle was started. Each ACBT cycle lased around 2 min and total treatment continued up to 15 minutes.

3. Results

40 bronchiectasis patients were assessed and were divided into two groups- Group A and Group B. Each group had a total of 20 patients (i.e N=20). The BCSS score, 6MWD and SGRQ score was assessed before and after the said interventions. Patients in Group A underwent ELTGOL therapy and Group B received ACBT as the airway clearance technique. All the data analysis was done using SPSS

software version 26. The intra-group analysis of BCSS score and total SGRQ score, pre and post intervention was done using Wilcoxon Signed Ranks test. The intra-group analysis of 6MWD, pre and post intervention was done using Paired t test. The inter-group analysis of BCSS score and total SGRQ score was done using Mann-Whitney test. The inter-group analysis of 6MWD was done using independent t test. In the entire study, the p value less than 0.05 is considered to be statistically significant.

Table 1: Gender distribution

			Group		Total	Test statistics
			A (ELTGOL)	B (ACBT)		
Gender	Male	Count	17	18	35	Fisher exact P value = 1.000
		% within Group	85.0%	90.0%	87.5%	
	Female	Count	3	2	5	
		% within Group	15.0%	10.0%	12.5%	
Total		Count	20	20	40	
		% within Group	100.0%	100.0%	100.0%	

Table 1 shows that out of the total number of participants i.e 40, the total number of male subjects were 35 (87.5%) and females were 5 (12.5%). In group A, out of the 20 subjects, 17 were males (85%) and 3 were females (15%). In group B, out of the 20 subjects, 18 were males (90%) and 2 were females (10%). The p value was 1.00 which makes the difference between the distribution of male and female subjects between two groups insignificant.

Table 2: Distribution of subjects according to BSI in each group.

			Group		Total	Test Statistics
			A (ELTGOL)	B (ACBT)		
BSI	Moderate	Count	14	15	29	Fisher Exact P value = 1.000
		% within Group	70.0%	75.0%	72.5%	
	Severe	Count	6	5	11	
		% within Group	30.0%	25.0%	27.5%	
Total		Count	20	20	40	
		% within Group	100.0%	100.0%	100.0%	

Table 2 shows that out of the total 40 subjects in the study, 29 subjects had moderate bronchiectasis (72.5%) and 11 subjects had severe bronchiectasis (27.5%). Out of the 20 subjects in Group A, 14 subjects had moderate bronchiectasis (70.0%) and 6 had severe bronchiectasis (30.0%). Out of the 20 subjects in Group B, 15 had moderate bronchiectasis (75.0%) and 5 had severe bronchiectasis (25.0%) The p value was 1.00 which makes the difference between distribution of moderate and severe bronchiectasis between two groups insignificant.

Table 3: Descriptive analysis of BCSS score pre and post intervention in Group A

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Pre BCSS	20	6.2000	1.82382	3.00	9.00	5.0000	6.0000	8.0000
Post BCSS	20	4.6000	1.53554	3.00	8.00	3.0000	4.5000	6.0000

Table 4: Wilcoxon signed ranks test to analyse data of BCSS score pre and post intervention in group A.

		N	Mean Rank	Sum of Ranks	Test statistics
Post BCSS – Pre BCSS	Negative Ranks	18	9.50	171.00	Z value
	Positive Ranks	0	.00	.00	-3.789
	Ties	2			P value
	Total	20			0.000

In table 3, it is seen that, in group A, the mean of BCSS score pre intervention is 6.2±1.82 with the minimum of 3.0 and maximum of 9.0 and that post intervention is 4.6±1.53 with the minimum of 3.0 and maximum of 8.0. The median value of BCSS score pre intervention is 6.0 and with 75% data less than 8.0. The median value of BCSS score post intervention is 4.5 with 75% data less than 6.0.

In table 4, using Wilcoxon signed ranks test, it was found that, in group A, 18 subjects had shown a negative rank and 2 subjects had shown a tie in the BCSS score between the pre and post intervention. Improvement in BCSS score is signified by reduction in the score. The p value was 0.00 and hence the difference in BCSS score post and pre intervention in Group A is statistically significant.

Magnitude of experimental effect is calculated using the Cohen's formula

Effect size (d) = $|Z| / \sqrt{N} = |-3.789| / \sqrt{20}$
$=0.847$

The effect size of 0.847 implies a large magnitude of interventional effect between pre and post observation.

Table 5: Descriptive analysis of BCSS score pre and post intervention in Group B

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Pre BCSS	20	6.1500	2.03328	3.00	11.00	5.0000	6.0000	8.0000
Post BCSS	20	4.1500	1.75544	1.00	9.00	3.0000	4.0000	5.0000

Table 6: Wilcoxon signed ranks test to analyse data of BCSS score pre and post intervention in group B.

		N	Mean Rank	Sum of Ranks	Test statistics
Post BCSS – Pre BCSS	Negative Ranks	18	9.50	171.00	Z value
	Positive Ranks	0	.00	.00	-3.771
	Ties	2			P value
	Total	20			0.000

In table 5, it is seen that, in group B, the mean of BCSS score pre intervention is 6.15±2.03 with the minimum of 3.0 and maximum of 11.0 and that post intervention is 4.15±1.76 with the minimum of 1.0 and maximum of 9.0. The median value of BCSS score pre intervention is 6.0 with 75% data less than 8.0. The median value of BCSS score post intervention is 4.0 with 75% data less than 5.0.

In table 6, using Wilcoxon signed ranks test, it was found that, in group B, 18 subjects had shown a negative rank and 2 subjects had shown a tie in the BCSS score between the pre and post intervention. Improvement in BCSS score is signified by reduction in the score. The p value was 0.00 and hence the difference in BCSS score post and pre intervention in Group B is statistically significant.

Magnitude of experimental effect is calculated using the Cohen's formula

Effect size (d) = $|Z| / \sqrt{N} = |-3.771| / \sqrt{20}$
= 0.843

The effect size of 0.847 implies a large magnitude of interventional effect between pre and post observation.

Table 7: Mann-Whitney test to compare the BCSS scores between Group A and Group B

	Group	N	Mean Rank	Sum of Ranks	Test Statistics
Pre BCSS	A (ELTGOL)	20	20.85	417.00	Z value=-0.195
	B (ACBT)	20	20.15	403.00	P value= 0.846
	Total	40			
Post BCSS	A (ELTGOL)	20	22.08	441.50	Z value=-0.871
	B (ACBT)	20	18.93	378.50	P value= 0.384
	Total	40			

In table 7, Using Mann Whitney test, it is seen that the pre intervention BCSS score of group A and group B had a mean rank of 20.85 and 20.15 respectively with the p value of 0.84 which infers that the difference in the pre intervention BCSS scores between the groups is insignificant hence comparable. It is also seen that the post intervention BCSS score of group A and group B had a mean rank of 22.08 and 18.93 respectively with the p value of 0.384 which infers that the difference in the post intervention BCSS scores between the groups is insignificant. Hence there is statistically insignificant difference seen in the BCSS score in group A and group B post respective interventions.

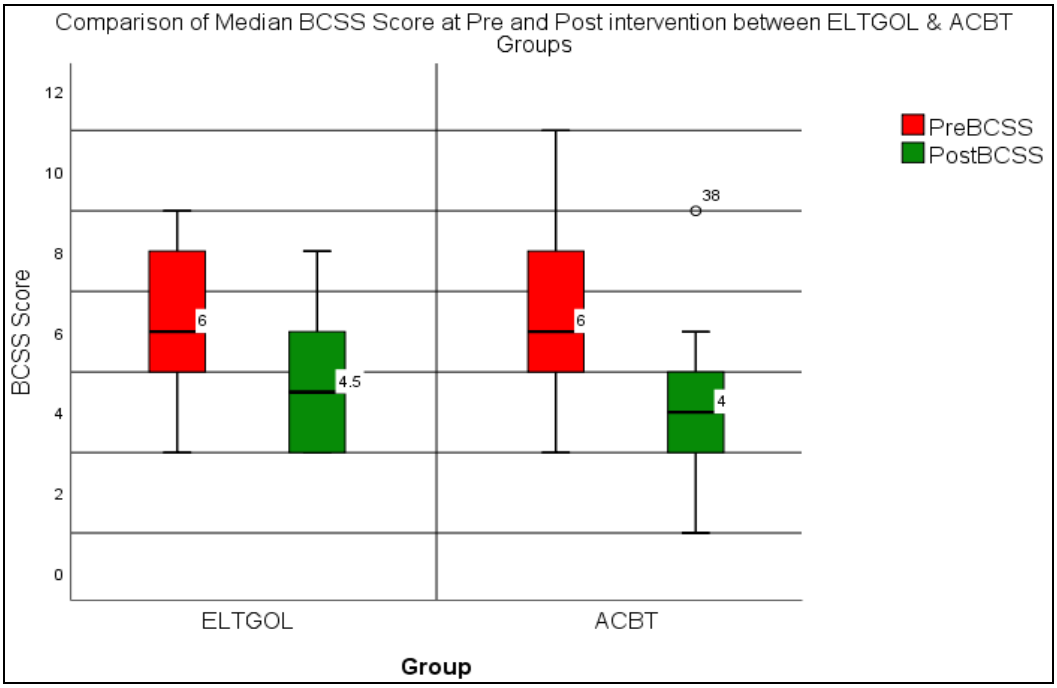

Fig 1: Graph representing the comparison of median BCSS score at pre and post intervention between group A and group B.

The box plot in Figure 1 compares the median BCSS score at pre and post intervention between group A and group B. For the pre intervention BCSS of group A (ELTGOL), minimum value= 3, lower quartile=5, median=6, upper quartile=8, maximum=9, range=6 and interquartile range (IQR)=3. For post intervention BCSS of group A, minimum value=3, lower quartile=3, median=4.5, upper quartile=6, maximum=8, range=5, IQR=3. In both the box plots for group A, IQR is not affected by outliers. For the pre intervention BCSS score of group B (ACBT), minimum=3, lower quartile=5, median=6, upper quartile=8, maximum=11, range=8, IQR=3. For post intervention BCSS of group B, minimum=1, lower quartile=3, median=4, upper quartile=5, maximum=9, range=8, IQR=2. In post intervention BCSS for group B, the IQR is affected by outliers.

Table 8: Descriptive analysis of 6MWD pre and post intervention in Group A

		Mean	N	Std. Deviation	Std. Error Mean
GROUP A	Pre 6MWD	333.16	20	104.88	23.45
	Post 6MWD	362.27	20	112.11	25.07

Table 9: Paired t-test to analyse data of 6MWD pre and post intervention in group A.

		95% Confidence Interval of the Difference		
		Lower	Upper	Sig. (2-tailed)
GROUP A	Pre6MWD- Post 6MWD	-36.08	-22.14	0.000

In table 8, it is seen that, in group A, the mean 6MWD pre intervention is 333.16±104.88 with SEM of 23.45 and in group B, the mean 6MWD post intervention is 362.27±112.11 with the SEM of 25.07.

In table 9, in group A, using the paired t-test, it is found that there is a statistically significant difference in the pre and post value of 6MWD [p = 0.00; (p<0.05)] with the lower limit of 22.14 and upper limit of 36.08. Magnitude of experimental effect is calculated using the Cohen's formula

Effect size (d) = Cohen's $d = (M_2 - M_1) / SD_{pooled}$

$SD_{pooled} = \sqrt{((SD_1^2 + SD_2^2)/2}$

M1- mean of 6MWD pre intervention

M2- mean of 6MWD post intervention

SD1- standard deviation pre intervention

SD2- standard deviation post intervention

d = 0.268

The effect size of 0.268 implies a small magnitude of interventional effect between pre and post observation.

Table 10: Descriptive analysis of 6MWD pre and post intervention in Group B

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Pre6MWD	368.34	20	129.99	29.07
	Post6MWD	394.84	20	128.51	28.74

Table 11: Paired t-test to analyse data of 6MWD pre and post intervention in group B.

		95% Confidence Interval of the Difference		
		Lower	Upper	Sig. (2-tailed)
GROUP A	Pre6MWD- Post 6MWD	-31.34	-21.66	0.00

In table 10, it is seen that, in group B, the mean 6MWD pre intervention is 368.34±12.99 with SEM of 29.07 and in group B, the mean 6MWD post intervention is 394.84±128.51 with the SEM of 28.74

In table 11, in group B, using the paired t-test, it was found that there is a statistically significant difference in the pre and post value of 6MWD [p = 0.00; (p<0.05)] with the lower limit of 21.66 and upper limit of 31.34.

Magnitude of experimental effect is calculated using the Cohen's formula

Effect size (d) = Cohen's $d = (M_2 - M_1) / SD_{pooled}$

$SD_{pooled} = \sqrt{((SD_1^2 + SD_2^2)/2}$

M1- mean of 6MWD pre intervention

M2- mean of 6MWD post intervention

SD1- standard deviation pre intervention

SD2- standard deviation post intervention

d = 0.205

The effect size of 0.205 implies a small magnitude of interventional effect between pre and post observation.

Table 12: Independent t-test to compare the 6MWD between group A and group B.

		Sig. (2 tailed)	Mean	Standard deviation	95% Confidence interval of the difference	
					lower	upper
Pre 6MWD	Group A (ELTGOL)	.352	333.16	104.88	-110.79	40.43
	Group B (ACBT)	.352	368.34	129.99	-110.89	40.537
Post 6MWD	Group A (ELTGOL)	.398	362.27	112.11	-109.77	44.63
	Group B (ACBT)	.399	394.84	128.52	-109.82	44.68

In table 12, Using Independent t-test, it is seen that the p value for the pre intervention between the two groups is p=0.352. This suggested that the pre values of the two groups were statistically comparable. Therefore, the two groups could be compared and analysed for any difference in their post 6MWD values. The pre intervention mean for 6MWD in group A was found to be 333.16±104.88 m and in post intervention mean is found to be 368.34±129.99 m as shown in figure 2

According to the analysis, the p value for the post intervention

between the two groups using the independent t-test was p=0.398 (p>0.05). This indicated a statistical insignificance in the post intervention 6MWD of the group A and group B. The mean of the post intervention 6MWD in group A is 362.27±112.11 m and that of group B is 394.84±128.52 m as seen in the figure 2. The level of significance was set at p=0.05 with the confidence interval of 95%.

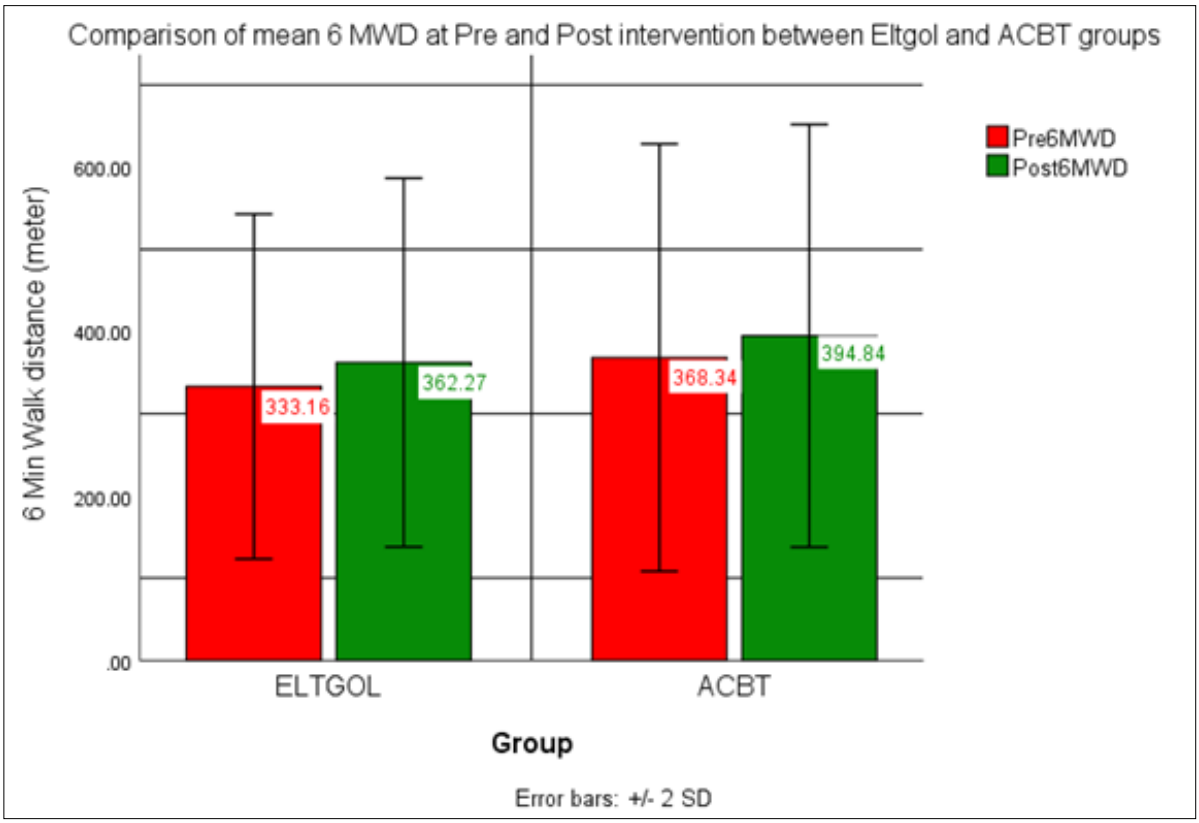

Fig 2: Graph showing the comparison of 6MWD at pre and post intervention between group A and group B

The graph in figure 2 shows the comparison of the mean 6-minute walk distance at pre and post intervention between group A and group B. In group A (ELTGOL), the mean 6MWD pre intervention is 333.16 whereas post intervention is 362.27. In group B (ACBT) the mean 6MWD pre intervention is 368.34 whereas post intervention is 394.84.

Table 13: Descriptive analysis of total SGRQ score pre and post intervention in Group A

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Pre-Score	20	43.3605	18.27	15.91	74.42	28.5575	44.26	56.93
Post-Score	20	35.0420	15.09	12.29	61.06	21.8225	34.87	47.43

Table 14: Wilcoxon signed ranks test to analyse data of total SGRQ score pre and post intervention in group A.

		N	Mean Rank	Sum of Ranks	Test Statistics
Post SCORE – Pre SCORE	Negative Ranks	18	11.50	207.00	Z value
	Positive Ranks	2	1.50	3.00	-3.808
	Ties	0			P value
	Total	20			0.000

In table 13, it is seen that, in group A, the mean of total SGRQ score pre intervention is 43.36±18.27 with the minimum of 15.91 and maximum of 74.42 and that post intervention is 35.04±15.09 with the minimum of 12.29 and maximum of 61.06. The median value of total SGRQ score pre intervention is 44.26 and with 75% data less than 56.93. The median value of total SGRQ score post intervention is 34.87 with 75% data less than 47.43

In table 14, using Wilcoxon signed ranks test, it was found that, in group A, 18 subjects had shown a negative rank and 2 subjects had shown a positive rank in the total SGRQ score between post and pre intervention. Improvement in total SGRQ score is signified by reduction in the total score. The p value was 0.00 and hence the difference in the total SGRQ score pre and post intervention in group A is statistically significant.

Magnitude of experimental effect is calculated using the Cohen's formula

Effect size (d) = |Z| /√N = |-3.808 | / √20
=0.851

The effect size of 0.851 implies a large magnitude of interventional effect between pre and post observation.

Table 15: Descriptive analysis of total SGRQ score pre and post intervention in Group B

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Pre SCORE	20	40.16	17.94	15.74	76.77	22.71	38.12	55.51
Post SCORE	20	35.14	17.00	8.51	71.12	18.15	35.45	49.71

Table 16: Wilcoxon signed ranks test to analyse data of total SGRQ score pre and post intervention in group B.

		N	Mean Rank	Sum of Ranks	Test Statistics
Post TSCORE – Pre TSCORE	Negative Ranks	19	10.95	208.00	Z value
	Positive Ranks	1	2.00	2.00	-3.845
	Ties	0			P value
	Total	20			0.000

In table 15, it is seen that, in group B, the mean of the total SGRQ score pre intervention is 40.16±17.94 with the minimum of 15.74 and maximum of 76.77 and that post intervention is 35.14±17 with minimum of 8.51 and maximum of 71.12. The median value of total SGRQ score pre intervention is 38.12 with 75% data less than 55.51. The median value of total SGRQ score post intervention is 35.45 with 75% data less than 49.71.

In table 16, using Wilcoxon signed ranks test, it was found that, In group B, 19 subjects had shown a negative rank and 1 subject had shown a positive rank in the total SGRQ score between the post and pre intervention. Improvement in the total SGRQ score is signified by reduction in the total score. The p value was 0.00 and hence the difference in the total SGRQ score pre and post intervention in group B is statistically significant.

Magnitude of experimental effect is calculated using the Cohen's formula

Effect size (d) = |Z| /√N = |-3.845 | / √20
=0.859

The effect size of 0.847 implies a large magnitude of interventional effect between pre and post observation.

Table 17: Mann-Whitney test to compare the total SGRQ score between Group A and Group B

	Group	N	Mean Rank	Sum of Ranks	Test Statistics
Pre TSCORE	ELTGOL	20	21.45	429.00	Z value = -0.514
	ACBT	20	19.55	391.00	P value = 0.607
	Total	40			
Post TSCORE	ELTGOL	20	20.65	413.00	Z value= -0.081
	ACBT	20	20.35	407.00	P value = 0.935
	Total	40			

In table 17, Using the Mann Whitney test, it was seen that the pre intervention total SGRQ score of group A and group B had a mean rank of 21.45 and 19.55 respectively with the p value of 0.607 which infers that the difference in the pre intervention total SGRQ score between the groups is insignificant hence comparable. It is also seen that the post intervention total SGRQ score of group A and group B had a mean rank of 20.65 and 20.35 respectively with the p value of 0.935 which infers that the difference in the post intervention total SGRQ score between the groups is insignificant. Hence there is statistically insignificant difference seen in the total SGRQ score in group A and group B post respective interventions.

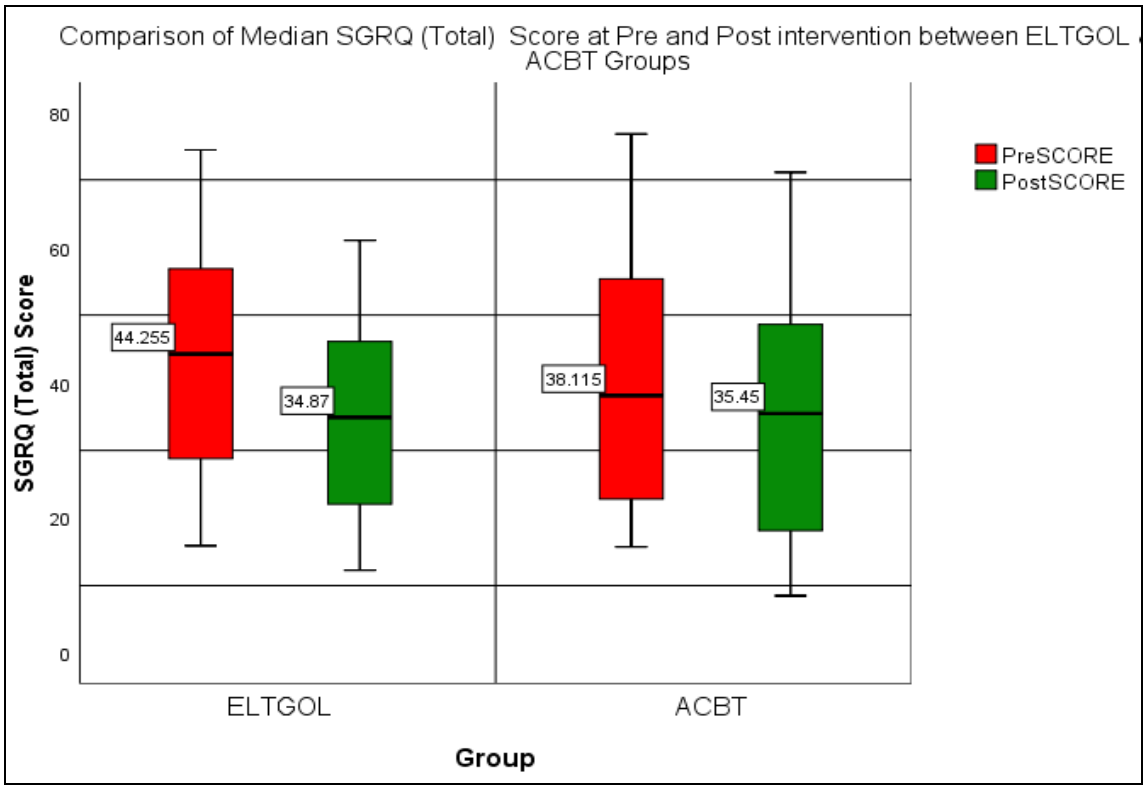

Fig 3: Graph representing the comparison of median total SGRQ score at pre and post intervention between group A and group B.

The box plot in Figure 3 compares the median SGRQ score at pre and post intervention between group A and group B. For the pre intervention SGRQ of group A (ELTGOL), minimum=15.91, lower quartile=28.56, median=44.26, upper quartile=56.93, maximum= 74.42, range=58.51, IQR=28.37. For post intervention SQRG of group A, minimum=12.29, lower quartile= 21.82, median=34.87, upper quartile=47.43, maximum=61.06, range=48.77 and IQR=25.61. For the pre intervention SGRQ of group B (ACBT), minimum=15.74, lower quartile=22.71, median=38.12, upper quartile=55.51, maximum=76.77, range=61.03, IQR=32.08. For the post intervention SGRQ of group B, minimum=8.51, lower quartile=18.15, median=35.45, upper quartile=49.71, maximum=71.12, range=62.61, IQR=31.56.

4. Discussion

The present study was designed to compare the efficacy of two airway clearance techniques *viz*. ELTGOL and ACBT in middle aged moderate to severe affected bronchiectasis patients. These techniques are widely used by respiratory physiotherapists and are proven safe for use. ACBT is widely used in India as a means of airway clearance technique whereas ELTGOL has gained popularity in the West as an effective airway clearance technique. The objective of this study was to compare the effectiveness of ELTGOL and ACBT in middle aged bronchiectasis patients in terms of breathlessness, cough, and sputum production score, 6-minute walk distance and St. George respiratory questionnaire after a 4-week intervention program.

Out of the total sample size of 40, this study involved 87.5% males and 12.5% females. All participants had moderate or severe bronchiectasis according to bronchiectasis severity index which includes various parameters such as % FEV1 predicted, number of hospital admissions, MMRC score, colonization of organisms and radiological severity. Scores above 5 was accepted for this study. The two groups were created by simple randomized sampling method. Both the study groups underwent a common treatment of nebulization with mucolytics or normal/hypertonic saline [39]. As per Will's analysis of pathophysiology of bronchiectasis, this disease causes reduction in the optimum levels of sodium and potassium which is essential for the muco-ciliary transport and thus nebulization with mucolytics or saline could possibly increase the salinity of the gel surface of the mucous which could help muco-ciliary clearance [40].

BCSS is a Likert questionnaire and measures the breathlessness, cough and sputum production and it provides an easy method to evaluate patient perception of these symptoms from visit to visit [41, 42] .Leidy *et al*., in 2003, conducted a trial on 2971 patients to evaluate the magnitude of mean change scores observed in the BCSS under various scenarios and concluded that a mean improvement of ≥1.0 on the BCSS total score is an indication that the study group has experienced dramatic relief with the treatment, changes of -0.6 to -0.7 represent moderate to-large symptomatic improvement; and mean changes at or near -0.35 indicate mild relief with the treatment [43].

As seen in table 3 and table 4, in the ELTGOL group, BCSS score pre intervention was 6.2±1.82 whereas post intervention was 4.6±1.53 and it suggested statistically significant difference (p= 0.00; p<0.05) after a 4-week intervention. The magnitude of change noted as d=0.847 which implied that there is a large clinical change observed in the treatment group. Kordic *et al*. [40] in 2009 also found a similar significant difference in the Borg scale and reduction in sputum volume after performing ELTGOL in COPD exacerbation patients for a week's intervention. Owing to the pathophysiology, this disease causes reduction in the recoil pressure for the movement of secretions due to the abnormal airway dilatation. Thus, the choice of decubitus position in this technique mobilizes secretion by three possible mechanisms- force of gravity, weight of mediastinum and pressure of abdominal viscera on the dependent lung [41]. All these factors along with additional manual abdominal compression towards the thorax given by the therapist with slow expiration from functional residual capacity to residual volume using a mouthpiece causes movement of secretions from more distal airways by the principle of gas- liquid interaction. In other words, as these factors tend to reduce the total cross-sectional area of the peripheral airways where mucus is primarily clogged, the velocity of airflow in the peripheral airways is increased [20] hence mobilizing the secretions. Abdominal compression component of ELTGOL possibly aids recoil pressure as Bronchiectasis involves reduction in the recoil pressure for the movement of secretions. The removal of secretions could have further reduced the work of breathing and hence the participants must have felt relief of the perception of breathlessness which is positively reflected as the decrease in BCSS score. Many participants reported cough immediately after a few slow expirations and had to expectorate immediately and reported a good immediate response to ELTGOL in the form of satisfaction of removal of secretions. Bellone *et al*. [42] compared the efficacy of postural drainage, ELTGOL and flutter in patients with exacerbation of chronic bronchitis and found that ELTGOL provides significant sputum production immediately, within 15 minutes and 1 hour post treatment which also supports the improvement in the BCSS score in this study. Lannefors and Wollmer [43] conducted a study on patients with cystic fibrosis to compare the efficacy of 3 techniques *viz*. postural drainage, positive expiratory pressure and exercise therapy and to study the effect on gravity on drainage of secretions. They used the ventilatory scintigraphy to measure mucous clearance and found surprising results. It was found that inspite of performing postural drainage only for the right middle lobe, the secretions were better cleared from the left dominant lobe which was contradicting the theoretical base of postural drainage, and which thus proves the principle of ELTGOL that uses a contra-gravitational position for the mobilization of secretions.

While assessing the BCSS score for group B (ACBT); mean for pre intervention was 6.15±2.03 whereas post intervention was 4.15±1.75 and it suggested statistically significant difference (p= 0.00; p<0.05) (table 5 and table 6). The magnitude of change noted as d=0.843 which implied that there is a large clinical change observed in the treatment group. The possible mechanisms leading to these results may be-The breathing control phase is reported to prevent bronchospasm while thoracic expansion exercise assists in loosening and clearance of secretions and improvement of collateral ventilation. The FET phase of ACBT is thought to promote secretion movement through changes in thoracic pressure and airway dynamics [22]. The slow and deep inspirations followed by end inspiratory hold promotes collateral ventilation through the alveolar pores of Kohn, Bronchiolar-alveolar channels of Lambert and inter-bronchiolar channels of Martins. In bronchiectasis, as there is a reduction in the recoil pressure due to the permanent dilation of airways, the thoracic expansion exercise by the virtue of added collateral ventilation assists in providing a

force for the movement of secretions out of vesicles and the FET phase helps to eliminate the secretions to the central airways by the principle of equal pressure point. This study has provided similar results as the study conducted by Syed in 2009 [44] which showed that ACBT improved the FEV_1/FVC ratio significantly. The improvement in FEV_1/FVC ratio further reduces the level of obstruction and relieves dyspnoea which might have reflected as an improvement of the breathlessness component of BCSS. ACBT in this study was administered in the semi fowlers position, the efficacy of which is proven by a research by Eaton *et al.* [45], who compared the semi fowlers position of ACBT with ACBT administered with postural drainage positions and concluded that ACBT-PD was associated with significantly more discomfort and interference with activities of daily life than ACBT and that the Borg dyspnoea scores did not change significantly with ACBT in standardized position and with postural drainage position. Thus, reduction of work of breathing due to removal of secretions could possibly be the reason for the improvement of the mean BCSS score.

While assessing the difference in BCSS score between group A and B (table 7), the difference in pre intervention BCSS score gives a p value of 0.84 which makes the groups comparable as the difference is insignificant and the difference in post BCSS score also gives a p value of 0.38 ($p>0.05$) which is statistically insignificant which infers that there is no statistically significant difference in the effectiveness of ELTGOL and ACBT in improving the BCSS score pre and post 4-week intervention. These results can be owing to the small sample size and limited study duration and intervention sessions within the study duration. Clinically it was observed that ELTGOL provided better elimination of mucous however a larger sample size with the given objective measure can better explain the difference between the two interventions.

Dyspnoea due to increased work of breathing (exertional dyspnoea) and physical fatigue due to chronic infection act as contributing factors to diminished physical function in bronchiectasis [52, 53]. Koulouris *et al.* conducted a study [54] on bilateral bronchiectasis patients to investigated whether expiratory flow limitation is present during tidal breathing and whether it is related to the exercise capacity in terms of maximal mechanical power output (WRmax) and found out that there is expiratory flow limitation present which correlates with higher levels of MRC dyspnoea which further correlates with reduction in the maximal mechanical power output. Maximal power output is checked by several functional exercise tolerance test and 6MWT is widely used in bronchiectasis patients [55].

Analysis of the 6MWD for group A (table 8 and table 9) shows that, mean of pre ELTGOL intervention was 333.16±104.88 whereas post intervention was 362.27±1122.10 and it suggested statistically significant difference ($p= 0.00$; $p<0.05$). However, the magnitude of change noted as $d= 0.268$ which implied that there is a small clinical change observed in the treatment group. Murray *et al.* [56] observed a similar significant improvement in the functional capacity however the outcome measure used was shuttle walk test and multiple airway clearance techniques were used and so it would be difficult to compare those results with the current study. Muñoz *et al.* [16] conducted a 1-year trail to study the efficacy of ELTGOL in a randomized placebo-controlled trial in terms of pulmonary symptoms and functional capacity and used the 6MWT to evaluate the later. The result of this study contradicts the current study with the p value of 0.746 between the groups indicating insignificant statistical differences. The significant statistical difference noted in this study could be due to the following possible mechanisms of ELTGOL-As ELTGOL causes elimination of secretions, it improves oxygenation. This mechanism has been proven in neonates in a study by Dall'Alba [57] who conducted a study to examine the effect of airway clearance on arterial blood gas report. Improvement in arterial oxygenation provides improvement in blood oxygenation saturation. This increase in oxygen saturation might have led to the improvement of the alveolar ventilation, optimization of V/Q mismatch and finally oxygen transport to the tissues [58]. As 6MWT is a test for submaximal exercise tolerance which aims to check the aerobic endurance of the participant, the liberation of more oxygen to the slow twitch muscles must have caused the improvement in the exercise capacity's outcome measure in this study.

For group B who underwent ACBT, mean of 6MWD pre intervention was 368.34±129.48 whereas post intervention was 394.84±128.51 and it suggested statistically significant difference ($p= 0.00$; $p<0.05$) (table 10 and table 11). However, the magnitude of change noted as $d= 0.205$ which implied that there is a small clinical change observed in the treatment group. A similar study was conducted by Elsayed *et al.* [59] on 45 bronchiectasis patients to evaluate the effect of ACBT on functional capacity using the 6MWT. In this study ACBT was administered 3 times a week for 2 months and it concluded that this technique shows significant and remarkable improvement in the functional capacity in bronchiectasis patients. Yang *et al.* [60] conducted a quasi-experimental trial to evaluate the efficacy of self-efficacy enhancing ACBT on functional capacity of lung cancer patients with lung resection and found that the technique significantly improves the functional capacity of the patients. As ACBT aims to clear secretions and improve collateral ventilation, it improves the vital capacity of the lungs and thus improves arterial oxygenation. Improvement in arterial oxygenation must have improved the peripheral perfusion and oxygen liberation for functional demand which must have led to activation of slow twitch muscles fibers which rely on aerobic supply to produce ATP. Thus, production of more ATP by the exercising muscles possibly causes improvement in the functional capacity of an individual which is reflected in the current study by improvement in the 6MWD post ACBT.

While observing the baseline difference in 6MWD in between group A and group B (table 12); the difference in pre 6MWD gives a p value of 0.266 ($p>0.05$) making the groups comparable for further analysis. However, after 4-week intervention with ELTGOL and ACBT, the differences observed in the 6MWD between the two groups gave a p value of 0.475($p>0.05$) making the difference between the two interventions statistically insignificant. As described by Verrill *et al.* [61], a pulmonary rehabilitation program of at least 12 weeks is appropriate to acquire optimal health benefits and functional capacity. The current study had a small sample size and a short study duration which could have caused the statistical insignificance. Further studies can be conducted to test functional capacity using different exercise tolerance tests using statistically significant sample size and longer study duration.

A study conducted by Wilson *et al.* [32] on 111 bronchiectasis patients validated the use of SGRQ scale in this population. In the current study, the mean SGRQ score of group A before ELTGOL was initiated was 43.63±18.27 and post 4-week

ELTGOL therapy was 35.04±15.08 and it suggested a statistically significant difference ($p<0.05$) (table 13 and table 14). The magnitude of change noted as d=0.851 which implied that there is a large clinical change observed in the treatment group. The reduction in SGRQ score was higher than the MCID of 4 unit [62]. These results are consistent with a previous study by Munoz *et al*. [16] in their 6- month intervention. Herrero *et al*. [17] studied the short-term effect of three slow expiratory airway clearance techniques including ELTGOL on quality of life in bronchiectasis patients using SGRQ and concluded that it has a positive impact on the quality of life on these patients. The significant improvement in SGRQ noted in this study can mostly be attributed to the reduction in the pulmonary impairments. As ELTGOL causes improvement in sputum elimination, it further causes improvement in alveolar ventilation, relieve in the perception of dyspnoea and reduction in the work of breathing. Reduced work of breathing causes decrease in fatiguability associated with bronchiectasis which could have led to the improvement of the quality of life.

In the ACBT group, SGRQ score pre intervention with ACBT was 40.15±17.93 whereas post intervention was 35.14±17.60 and it suggested statistically significant difference ($p<0.05$) (table 15 and table 16). The magnitude of change noted as d=0.859 which implied that there is a large clinical change observed in the treatment group. The reduction in SGRQ score higher than the MCID of 4 units. A similar study conducted by Halim *et al*. [63] in the year 2016 revealed similar improvement in LCQ score in ACBT group. Reduced feeling of dyspnoea and active elimination of secretions possibly could be the reason for improvement in the SGRQ score. As ACBT aims to improve collateral ventilation and elimination of secretions, there is improvement in the oxygenation and ventilation of the lung which indirectly improves the saturation of blood with oxygen thus providing more oxygen for aerobic endurance activities of the day-to-day life and hence must be improving the quality of life. A study by Naswa *et al*. [64] stated that ACBT helps to improve the chest x-ray and reduce the length of hospital stay which are also markers of improvement in quality of life in patients post valve replacement.

The difference in the total SGRQ score between group A and group B before the initiation of intervention gave a p value of 0.60 which made the groups comparable ($p>0.05$) and difference in post intervention total score gives a p value of 0.935 which is statistically insignificant infers that there is no statistically significant difference in the effectiveness of ELTGOL and ACBT in improving the SGRQ score pre and post 4-week intervention. Most of the studies on pulmonary rehabilitation have evaluated its effect on quality of life after a long duration trial up to 24 weeks. The short duration and small sample size of the current study could have possibly caused the statistical insignificance. Further long-term interventions could be taken up to understand the role of ELTGOL and ACBT in improving the quality of life of bronchiectasis patients.

The study thus concludes that individually, ELTGOL and ACBT has a statistically significant role in improving the pulmonary impairments, exercise capacity and quality of life in bronchiectasis patient and these techniques are equally effective in improving these parameters.

5. Conclusion

- There is a significant difference in the effectiveness of ELTGOL therapy in terms of improving the pulmonary impairments, functional capacity and health related quality of life in middle aged Bronchiectasis patients.
- There is a significant difference in the effectiveness of ACBT in terms of improving the pulmonary impairments, functional capacity and health related quality of life in middle aged Bronchiectasis patients.
- However, there is insignificant difference between ELTGOL and ACBT in terms of improving the pulmonary impairments, functional capacity and health related quality of life in middle aged Bronchiectasis patients.

6. Clinical Implications

Bronchiectasis is characterized by chronic cough and sputum production. According to this study it can be clinically implied that ELTGOL is an easy to administer, safe and is proven effective in Bronchiectasis patients and can be given in elderly and physically debilitated patients with excessive sputum production and in whom active participation is less as this therapy is equally effective as ACBT.

7. Conflict of interest: The authors declared no conflict of interest

8. Acknowledgement: We want to thank all the participants of the study for participating and allowing us to use the clinical findings in the study. We also want to thank RWS Life Sciences and Astra Zeneca for granting the permission to use the breathlessness cough and sputum scale, and St George University of London for granting the permission to use the St George Respiratory Questionnaire as an outcome measure for the study.

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